

Food and Drug Administration  
Rockville MD 20857

AUG 23 1990

Re: Ergamisol  
Docket No. 90E-0266

Charles E. Van Horn  
Patent Policy and Projects Administrator  
Office of the Assistant Commissioner for Patents  
U.S. Patent and Trademark Office  
Crystal Park Building 2, Suite 919  
Washington, D.C. 20231

Dear Mr. Van Horn:

This is in regard to the application for patent term extension for U.S. Patent No. 4,584,305 filed by Johnson and Johnson under 35 U.S.C. 156. The human drug product claimed by the patent is Ergamisol (levamisole HCl), New Drug Application (NDA) No. 20-035.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use as a human drug product for the active ingredient, levamisole HCl. Levamisole HCl had previously received permission for commercial marketing or use as an animal drug.

The NDA was approved on June 18, 1990, which makes the submission of the patent term extension application on August 1, 1990, timely within the meaning of 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

*Ronald L. Wilson*  
Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs

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cc: Robert L. Minier  
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